

REMARKS

By this amendment, Claims 1 and 3 have been amended in order to place these claims in proper form and to overcome certain objections of the Examiner. In particular, the subject matter of Claim 10 has been incorporated into Claim 1, and Claim 10 is accordingly canceled without prejudice. Claims 4 and 5 have also been canceled without prejudice. Claim 12, which was originally dependent on canceled Claim 10 has been rewritten as new Claim 35, and the previous Claim 12 is also canceled without prejudice. All of these amendments are supported by the original application and no new matter has been added. Claims 1-3 and 35 are currently being examined, with the remaining claims considered withdrawn as non-elected. For reasons as set forth below, Applicants submit that the outstanding rejections are respectfully traversed and that this case is in condition for allowance.

In the Official Action, the Examiner had objected to the Abstract as not descriptive. Without addressing the merits of this objection, the objection has been traversed in that Applicants have provided herewith a revised Abstract of the Disclosure.

In the Official Action, the Examiner objected to the claims on the grounds that the root mean square deviation increased in the dependent claims. Without addressing the merits of this objection, Applicants have amended the claims to obviate the objection.

In addition, there was an objection to the specification that it did not disclosed region IIIA as claimed. Contrary to the Examiner's position, the residues from human serum albumin that form the binding sites for region IIIA are disclosed at Table III, page 54 of the specification (and now in amended Claim 1), and the Examiner's objection is respectfully traversed.

In the Official Action, the Examiner made several rejections under 35 U.S.C. §112, second paragraph, and these rejections are respectfully traversed. For example, the claims refer to the structural binding coordinates at the residues or positions referred to in Table III, and one skilled in the art would readily understand what is being referred to. In addition, the method steps iv-vi in Claim 1 have been corrected; and Claims 4-5 have been canceled without prejudice. Claim 1, which incorporates the subject matter of canceled Claim 10, is based on the sites as disclosed in Table III for binding region IIIA; and these are set forth directly in the table and are not indefinite. Finally, Claim 12 has been rewritten as new Claim 35, and this claim avoids the previous objection under Section 112. Accordingly, Applicants submit that the present claims are proper under Section 112, and that the Examiner's rejections on the basis of this provision are respectfully traversed.

In the Official Action, the Examiner rejected the claims under 35 U.S.C. §101 as not being statutory subject matter. Under the recent decision of *In re Bilski*, 88 U.S.P.Q.2d 1385 (Fed. Cir. 2008), a claim is patentable subject matter if it is (1) is implemented with a particular machine or apparatus; or (2) transforms an article from one state to another. As amended, the present claims incorporate an apparatus or machine devised in order to carry out the process, and this constitutes statutory subject matter under 35 U.S.C. §101. Thus, the Examiner's rejection on this basis, insofar as applied to the claims as amended, is respectfully traversed and should be withdrawn.

In the Official Action, the Examiner made a rejection under 35 U.S.C. §112, first paragraph, and this rejection is respectfully traversed. As stated above, the claims now

refer to the structural binding coordinates at the residues or positions referred to in Table III, and one skilled in the art would readily understand what is being referred to.

In the Official Action, the Examiner rejected Claims 1-5, 10 and 12 under 35 U.S.C. §103 as being obvious over the Carter US patent 5780594 in view of the 2003 Colmenarejo article and the Floriano US patent publication 2002/0099506. Applicants contest this rejection for many reasons, including the fact that the Colmenarejo article is not prior art to the present claims. Moreover, it is clear that the present invention goes beyond any prior teaching and provides for the first time a method by which a more accurate predictive tool can be obtained with regard to binding of a possible drug to human serum albumin. For example, one of the discoveries of the present invention was the accurate determination of the placement of drugs at the particular binding sites which allows for an improved predictive tool with regard to drug interactions. It is further clear that no prior art reference teach or suggest the specific ability to identify compounds and their binding interactions with albumin in the manner claimed in the present application, and indeed the prior art references such as Floriano actually teach away from the present invention because they do not disclose or suggest obtaining an accurate picture of the binding coordinates of the albumin-drug complex, nor using that information to evaluate the results of computer fitting operations and determine the ability of that drug to bind with albumin at particular sites. Since the drug-albumin interaction may be important in terms of the effectiveness of the drug, the information obtained by virtue of the process of the present invention will be an invaluable predictive tool in assessing the effectiveness of drugs on the basis of their interactions and association with albumin.

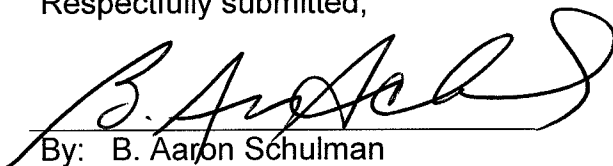
Accordingly, this rejection, insofar as applied to the claims as amended, is respectfully traversed and should be withdrawn.

Finally, the Examiner rejected the claims on the basis of co-pending application Serial No. 10/555,761. As amended, it is clear that the claims in the present application are no longer in conflict, and the Examiner's rejection on this basis is respectfully traversed.

In light of the above amendments and arguments, Applicants submit that the outstanding rejections and objections have been traversed, and that the present application is now in condition for immediate allowance. Such action is respectfully requested.

Respectfully submitted,

Date: July 14, 2009


By: B. Aaron Schulman
Registration No.: 31,877

STITES & HARBISON PLLC ♦ 1199 North Fairfax St ♦ Suite 900 ♦ Alexandria, VA 22314
TEL: 703-739-4900 ♦ FAX: 703-739-9577 ♦ CUSTOMER No. 000881